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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,446

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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

04/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,446	Applicant(s) UEDA ET AL.	
	Examiner Sudhakar Katakam	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the application

1. Receipt of Applicant's request for continued examination filed on 6th March 2009 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6th March 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 10 recites "ascorbic acid or a related compound thereof" but there is no indication as to how a compound within the scope of the limitation is related to ascorbic acid. For example, ascorbic acid is a vitamin. Are related compounds vitamins? Ascorbic acid is also an antioxidant. Is any antioxidant a related compound according to the claim limitation? Must the related compound have some structural similarity to ascorbic acid? If so, what is the defining structural similarity? Therefore, it

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is impossible to determine the metes and bounds of the claimed subject matter.

Therefore, claim 10 is rendered indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merck & Co., Inc** (GB 947,643) and applicants' acknowledged prior art in view of **Kijima et al** (US 4,061,660), **Kijima et al** (US 4,039,573) and **Morita et al** (US 4,163,864).

Merck & Co teaches preparation and purification of reduced coenzyme Q₁₀ from the oxidized form of coenzyme Q₁₀ in ethanol and adding excess of sodium borohydride in aqueous medium and the resulted yellow orange compound is diluted with water and the compound is extracted with petroleum ether. The petroleum extracts are washed with water and then dried, which results in crystallized form of reduced coenzyme Q₁₀,

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the pure hydroquinone of coenzyme Q₁₀. This may be recrystallized from alcohol-petroleum ether mixture. **Merck & Co** teachings also do not use chromatographic purification steps.

Applicants' specification acknowledges the impurities present in the reduced coenzyme Q₁₀ such as oxidized coenzyme Q₁₀, reducing agents such as sodium borohydride, and known reducing agents such as zinc and vitamin C species [see page 1 of the specification].

The difference between the instant claims and the **Merck & Co** is that in the instant claims comprises washing crystals with water-soluble organic solvents and thereby remove a water-soluble impurities from the crystals, whereas **Merck & Co** teaches washing petroleum extract with water and then dried to get the pure crystals and this may be recrystallized with alcohol-petroleum ether mixture.

Washing and purifying crystals is a well known process in the art. It is desirable to use suitable solvents in which impurities get dissolved. **Merck & Co** is silent on the applicants' solvents; However, **Merck & Co** clearly suggested recrystallization with alcohol-petroleum ether mixture. It is a common practice to use suitable solvents for washing/purifying the crystals. For example, in the analogous situation of purification of similar compounds, the crystals are washed with water soluble organic solvents. **Kijima et al** (US 4,061,660) teach washing of crystals with diethyl ether [see Example 1]. **Kijima et al** (US 4,039,573) additionally discloses an analogous washing process where zinc is the catalyst [see Example 3]. **Morita et al** (US 4,163,864) also shows an analogous washing process, where methanol is used for washing [see Example 1].

In summary, **Merck & Co** teaches preparation and purification of reduced coenzyme Q₁₀ from the oxidized form of coenzyme Q₁₀ in ethanol and adding excess of sodium borohydride. Applicants' specification acknowledges the impurities present in the reduced coenzyme Q₁₀. An analogous prior art teaches the use of water soluble organic solvents in washing the crystals to remove the impurities.

The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to start with the **Merck and Co** teachings and combine the teachings of known solvents for the purification process, to achieve the instant claims with a reasonable expectation success. It is after all a simple washing to remove impurities using suitable solvents. The selection a solvent is depends on the solubility

of the impurities. Applicants are invited to provide a showing which is commensurate in scope with the claimed invention that clearly demonstrate that the claimed purification step results in some unexpected property over the prior art. Absent any showing of unusual and/or unexpected results, the art obtains the same effect on the purification of reduced coenzyme Q10. The expected result would be an improved purification of reduced coenzyme Q10 for the chemical industry.

Modifying such parameters is prima facie obvious because an ordinary artisan would be motivated to optimize the purification process to make the process more economical, since it is within the scope to exchange the solvents through a routine experimentation.

Response to Arguments

7. Applicant's arguments filed on 6th March 2009 have been fully considered but they are not persuasive.

The examiner acknowledges applicants' argument that **Merck & Co.** product necessarily contains water-soluble impurities, particularly the reducing agent and/or impurities derived from the reducing agent, and **Merck & Co.** does not even imply washing of crystals.

The examiner contends, however, that the independent claims do not require the source of impurity. Even if the claim has such limitation, the selection of solvent is depends on the chemical properties of impurities. **Merck & Co.** teach a solvent which removes water-soluble impurities. It is desirable to use suitable solvents in which impurities get dissolved. **Merck & Co.** also suggested the recrystallization of reduced

coenzyme Q10 with alcohol-petroleum ether mixture. However, the secondary references also teach washings of structurally similar compound with water soluble organic solvents.

The examiner acknowledges applicants' argument that the secondary references do not teach washing crystals or oily form of the product with a water-soluble organic solvent or a mixture of a water-soluble organic solvent and water.

The examiner contends, however, that **Kijima et al** (US 4,061,660) teach, in an analogous compound, washing of crystals with diethyl ether [see Example 1]. **Kijima et al** (US 4,039,573) additionally discloses an analogous washing process where zinc is the catalyst [see Example 3]. **Morita et al** (US 4,163,864) also shows an analogous washing process, where methanol is used for washing [see Example 1].

With regard to the applicants' comparative experiments and statements on the difference in the solvents used in the purification process, please note that the mere statements by the inventors are not supported by evidence. In Table 1 of specification, the comparison provided is between an aqueous ethanol solution and pure water while the solvent suggested by the prior art is, e.g., diethyl ether or methanol. Therefore, the comparison with water is not a comparison to the closest art. Applicants need to show beneficial of their process over the closest prior art in a side by side comparison. These should be in the form of either a declaration or an affidavit.

Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references

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themselves or in the knowledge generally available to one of ordinary skill in the art.

See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is permissible for the Examiner to rely on disclosures, which fairly teach embodiments of Applicant's invention. The claims require a multitude of elements and it is reasonable for one of ordinary skill in the art to consider these elements being used together.

Conclusion

8. No claim is allowed in absence of a clear delineation of the claims from the prior art and a side by side showing of unexpected results commensurate in scope of the claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621

/Daniel M Sullivan/
Supervisory Patent Examiner, Art Unit 1621